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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,072	03/11/2004	Zhongming Zeng	1004-0102.01	5696

26568 7590 02/07/2007

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EXAMINER	
TELLER, ROY R	
ART UNIT	**PAPER NUMBER**
1654	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,072	ZENG, ZHONGMING	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *2,3 and 5-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ~~9/29/06~~. 7/19/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the election, received 9/29/06, in which applicant elected the combination of all five amino acids: glutamic acid, aspartic acid, isoleucine, phenylalanine and proline. Applicant further elected sodium salts of the five amino acids and the anti-fungi drug: fluconazole. The elected species read on claims 1, 4, 12, and 13.

Claims 2-3, and 5-11 are withdrawn as being drawn to a non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1, 4, 12 and 13 are pending.

Information Disclosure Statement

The information disclosure statement, received 7/19/04, is acknowledged. A signed copy is enclosed hereto.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 12 and 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,770,306, in view of Sobel et al. (American Journal of Obstetrics and Gynecology, 1995, vol. 172, pp-1263-8) . Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application is drawn to a vaginal use composition for treating a patient suffering from abnormally high acidity in the vaginia, wherein the vaginal pH value is lower than 4.0, the said composition consisting essentially of all of the following amino acids: glutamic acid, aspartic acid, isoleucine, phenylalanine, and proline; an effective amount of an anti-fungal drug (fluconazole), a sufficient amount of pharmaceutically acceptable acid or alkali which results in a pH of the composition from 4.0-8.0; and one or more pharmaceutical carriers.

The '306 patent recites a method of treating abnormally high acidity in the vagina, comprising: providing a pharmaceutical formulation consisting essentially of an effective amount of a composition comprising the following amino acids: glutamic acid, aspartic acid, isoleucine, phenylalanine, and praline, a sufficient amount of pharmaceutically acceptable acid or alkali, which results in a pH of the composition from 4.0-8.0, and one or more pharmaceutical carriers.

Sobel et al. (American Journal of Obstetrics and Gynecology, 1995, vol. 172, pp-1263-8) discloses *Candida* vaginitis is currently treated with a wide range of intravaginal preparations. The antifungal drug, Fluconazole has a marked activity against *Candida* vaginitis and favorable pharmacokinetics. Sobel excluded patients from the study if the patient had a vaginal pH above

4.5, to study the efficacy of fluconazole against *Candida* vaginitis. Sobel concluded that fluconazole proved to be a safe and effective treatment for *Candida* vaginitis. See, i.e., for example, abstract and page 1264.

The MPEP states that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose...[T]he idea of combining them flows logically from their having been individually taught in the prior art. See MPEP 2144.06. Since the US patent claims treating vaginitis using the amino acid composition and Sobel teaches treating vaginitis using fluconazole, it would have been obvious to combine them in a single composition. Further, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have combined the vaginal use composition for treating a patient suffering from abnormally high acidity in the vaginia, wherein the vaginal pH value is lower than 4.0 of the '306 patent with the beneficial teachings of Sobel, because Sobel discloses the use of an antifungal drug when the patient's vaginal pH is below 4.5.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT
1654
1/3/07
RT

1/18/07
ANISH GUPTA
PRIMARY EXAMINER